UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KELLY and HARRY KRONBERG, individually and the marital community composed thereof, Plaintiffs, v. JOHNSON & JOHNSON, INC., a New Jersey Corporation and DEPUY ORTHOPAEDICS, INC., an Indiana Corporation, Defendants.	No. COMPLAINT **JURY TRIAL DEMANDED**

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COMES NOW Kelly and Harry Kronberg, Plaintiffs, and allege as follows:

I. INCORPORATION

1. By this reference, each paragraph contained herein is incorporated as support for each paragraph which follows.

II. PLAINTIFFS

2. Plaintiffs Kelly and Harry Kronberg, husband and wife, were, at all times relevant, residents of Snohomish County, Washington.

3. When not otherwise specified, the terms "plaintiffs" shall refer collectively to Kelly and Harry Kronberg.

III. DEFENDANTS: JOHNSON & JOHNSON & DEPUY

4. On information and belief, Defendant Johnson & Johnson ("J&J"), is a New Jersey corporation doing business in the State of Washington. On information and belief, Defendant Depuy ("Depuy") is an Indiana corporation doing business in the State of Washington. On information and belief, Depuy is a subsidiary of J&J.

5. At all times material hereto, Depuy was acting as a subsidiary of J&J. J&J is therefore vicariously liable for the acts and/or omissions of Depuy described herein under the legal theories of master and servant, principal and agent, and respondeat superior. When not otherwise specified, the term "defendants" shall refer collectively to J&J and Depuy.

IV. JURISDICTION AND VENUE

6. Jurisdiction and venue are proper pursuant to 28 U.S.C. § 1332. There exists complete diversity between the parties and the amount in controversy exceeds $75,000.00.

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V. STATEMENT OF FACTS

A. Facts Regarding Defendants' Design, Manufacturing, Marketing and Sale of ASR Device

7. At all times relevant, Defendants developed, manufactured, promoted, distributed and sold the ASR hip replacement system ("ASR system") that is the subject of this lawsuit throughout the United States and other countries.

8. On information and belief, the design for the ASR system was completed by 2005. The ASR system is made from cobalt chrome metal and places the metal femoral head directly in contact with a metal acetabular cup, without a liner or buffer between the head and the socket.

9. The ASR system is classified as a Class III medical device. Class III medical devices are those that operate to sustain human life, are of substantial importance in preventing human impairment, or pose potentially unreasonable risks to patients utilizing the device.

10. The Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA"), typically requires Class III medical devices like the ASR system to undergo a pre-market approval process. This process obligates the device manufacturer and/or designer to implement a clinical investigation concerning the effects of the device and to report the findings to the Food and Drug Administration ("FDA").

11. The pre-market approval process is rigorous, typically requiring the submission of an application that includes, among other items, reports of all studies and/or investigations of the device's safety and effectiveness that have been published or reasonably known to the applicant. The pre-market approval process also requires a full statement of the device's components, properties and the principle(s) of operation, as well as, a full description of the manufacturing

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process involved. The FDA will only grant pre-market approval if it finds there is reasonable assurance that the device is safe and effective, weighing the probable benefit of the device against any possible risk of injury or illness from its use.

12. However, a medical device on the market prior to the effective date of the MDA is not required to undergo the rigorous pre-market approval process described immediately above. These types of devices are commonly called "grandfathered devices."

13. In addition, a medical device marketed after the MDA's effective date has the option to bypass the pre-market approval process by claiming that the device is "substantially equivalent" to a "grandfathered" pre-MDA device. This second exception to the pre-market approval process is commonly known as the "510(k) process" and requires the manufacturer and/or designer to notify the FDA under section 510(k) of the MDA of its intention to market the device as "substantially equivalent" to a "grandfathered device," ninety days prior to the device's introduction to the market.

14. The MDA does not require an FDA determination that a device is safe and/or effective when a manufacturer and/or designer claims that a device is "substantially equivalent" to a "grandfathered device."

15. In 2005, Defendants elected to market the ASR system by obtaining FDA approval pursuant to section 510(k). Consequently, the ASR system did not undergo the rigorous pre-marketing process contemplated for Section III medical devices, including clinical testing and/or trials. In August 2005, the FDA approved Defendant's request pursuant to section 510(k) of the MDA finding that the device is "substantially equivalent" to another device introduced prior to the effective date of the MDA.

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16. However, the FDA did not conclude that the ASR system was either safe or effective as a medical device. In fact, the FDA notified defendants that its determination of substantial equivalence "does not mean the FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies."

17. Soon after the ASR system entered the market, reports of problems with the device, including an abnormally high failure rate, were made known to Defendants. Reports from around the world, including studies from Australia and the United Kingdom, reflected that the ASR system was failing at a substantially higher rate compared to similar products. One of the causes of the failure rate of the ASR system relates to the extremely shallow metallic acetabular cup and/or femoral ball characterizing the device.

18. No later than 2007, Defendants knew of the design and manufacturing concerns surrounding the ASR system but did not notify patients or doctors affected by the problem. Instead, Defendants insisted that the ASR system was superior to similar devices offered by competitors and continued to aggressively market the system.

19. In 2007, Australia's National Joint Replacement Registry notified Defendants, on numerous occasions, that there were far higher than expected failure and revision rates for the ASR system.

20. During the same time frame, Defendants were made aware that patients who were implanted with the ASR system were far more likely to experience elevated metal ion concentration resulting from debris ejected from the device. Despite these concerns, Defendants did not alert the public and continued to assert that the ASR system was safe.

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21. By the end of 2009, the ASR system was recalled in Australia. However, Defendants continued to sell the device throughout the rest of the world, despite data showing that its revision rate was approximately 15% five years after surgery.

22. In early 2010, Defendants announced that they were phasing out the ASR system due to declining sales. Defendants' announcement did not mention the high failure rates that were being reported throughout the world.

23. In August 2010, Defendants announced a nationwide recall related to the ASR system. On or about August 25, 2010, Defendants confirmed that approximately 13% of patients who had received the ASR system as a part of a total hip replacement surgery would require revision surgery within five years of implantation.

B. Facts Regarding Plaintiffs' Injuries

24. Kelly Kronberg is a 56 year-old woman who lives in Mukilteo, Washington with her husband, Harry. Ms. Kronberg has worked as an engineer at the Boeing Company for most of her adult life.

25. In September 2008, Ms. Kronberg underwent a total right hip replacement. A total hip replacement results in the body's natural hip joint being replaced by artificial components often comprised of metal and plastic.

26. As a part of the surgery, Ms. Kronberg's surgeon implanted an ASR system.

27. At the time of her surgery, neither Ms. Kronberg, nor her surgeon, were aware of the manufacturing and design flaws associated with the ASR system.

28. In late 2012, Ms. Kronberg began to experience swelling in the area near the incision for her right hip replacement.

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29. By April 2013, large amounts of fluid began to collect near the location of Ms. Kronberg's ASR system implantation.

30. Ms. Kronberg's surgeon ordered that an MRI be performed of her right hip. Ms. Kronberg was diagnosed with an infection and inflammatory reaction due the internal joint prosthesis. Ms. Kronberg was also suffering from pain in the joint and pelvic region, also associated with the ASR system.

31. After April 2013, Ms. Kronberg continued to suffer from pain in her hip, groin and buttock areas. Consequently, the decision was made to perform a revision surgery and remove the defective ASR system.

32. On June 12, 2013, Ms. Kronberg underwent revision surgery on her right hip. Ms. Kronberg's post-operative diagnoses included "failed right total hip arthroplasty with presumed metal hypersensitivity." The surgeon also noted a large amount of fluid collection, with a cystic mass and evidence of "trunnion metallosis."

33. In the weeks following surgery, Ms. Kronberg missed a substantial amount of work. In addition, she has experienced substantial pain and suffering resulting from the surgery.

34. As a result of her injuries alleged herein, plaintiffs have suffered great personal loss, including loss of consortium.

VI. PRODUCTS LIABILITY – NEGLIGENT DESIGN

35. Defendants are product manufacturers within the meaning of RCW 7.72.010.

36. Defendants negligently designed manufactured, marketed and/or sold the ASR system, including but not limited to:

a. Defendants failed to properly test the ASR system before releasing the device to the market;

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b. Defendants failed to conduct appropriate post-market testing and/or monitoring of the ASR system;

c. Defendants negligently designed the ASR system resulting in an acetabular cup that is too shallow and/or allowed the metal cup to grind on the metal femoral ball.

37. As a direct and proximate result of Defendants' negligence, plaintiffs were damaged in an amount to be established by a jury following trial.

VII. PRODUCTS LIABILITY – FAILURE TO WARN

38. Since at least 2007, Defendants knew that there existed problems with the ASR system, including an unusually high failure rate and/or high incidence rate of metallosis in individuals who had been implanted with the device.

39. Despite numerous reports of problems from doctors and experts throughout the world, Defendants did not warn the public, Ms. Kronberg or her doctors of the danger relating to the ASR system.

40. As a direct and proximate result of Defendants' negligence, plaintiffs were damaged in an amount to be established by a jury following trial.

PRODUCTS LIABILITY - BREACH OF EXPRESS AND IMPLIED WARRANTY

41. Defendants aggressively advertised, labeled, marketed and promoted the ASR system to healthcare providers and patients after it came to market in 2005.

42. Defendants represented that the ASR system was safe and effective for hip replacement surgery, including the hip replacement surgery Ms. Kronberg underwent in September 2008. Defendants further warranted that the ASR system's performance was based upon a strong clinical history, was designed to reduce wear and/or that the ASR system was designed for younger, more active individuals needing hip replacement surgery.

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43. The representations made by Defendants regarding the qualities and performance of the ASR system constitute affirmative affirmations of fact and/or promises regarding the ASR system, became a part of the benefit of the bargain between Defendants and plaintiff and constitute express and/or implied warranties regarding the ASR system.

44. At all times material, plaintiffs utilized the ASR system for the purpose and in the manner intended by Defendants.

45. The ASR system did not conform to the representations made by Defendants in that the device was not safe, did not reduce wear and was not clinically shown to benefit younger individuals needing hip replacement surgery. In addition, the ASR system was not reasonably fit for the ordinary purposes for which such devices are used and did not meet the expectations for the performance of the product despite being used in a customary, usual and reasonably foreseeable manner.

46. Plaintiffs were injured as a direct and proximate result of Defendants actions, omissions and/or misrepresentations and suffered damages in an amount to be decided by a jury following trial.

VIII. PRAYER FOR RELIEF

Wherefore, Plaintiffs request that the Court enter judgment against defendant in the following fashion:

A. The full amount of Plaintiffs' special damages;

B. The full amount of Plaintiffs' general damages;

C. Exemplary damages to the full extent allowed by law;

D. The full amount of Plaintiffs' damages for loss of consortium;

E. Plaintiffs' attorneys' fees and costs;

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F. Prejudgment interest on Plaintiffs' damages; and

G. Such other and further relief the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

DATED: August 9, 2013

HAGENS BERMAN SOBOL SHAPIRO LLP

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By: /s/Marty McLean

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